

What is Claimed:

1 1. An introducer for insertion in a lumen from a proximal location outside
2 the lumen to a distal location within the lumen for deployment of a prosthesis at a junction of
3 a main lumen and at least one branch lumen, the introducer comprising:

4 an outer sheath having a distal end;

5 an axial guide wire slidable within the outer sheath;

6 at least one peripheral guide wire slidable within the outer sheath;

7 a nose cone located at the distal end of the outer sheath, the nose cone having
8 a periphery, an axial conduit slidable over the axial guide wire, and at least one peripheral
9 channel spaced apart from the axial conduit for receiving one of the peripheral guide wires.

1 2. The introducer of claim 1, wherein each peripheral channel is open to
2 the periphery of the nose cone.

1 3. The introducer of claim 2, wherein each peripheral channel provides
2 communication between an interior of the introducer and the lumen when the nose cone is
3 positioned at the distal end of the sheath.

1 4. The introducer of claim 1, wherein each peripheral guide wire
2 comprises an expandable balloon at a distal end thereof.

1 5. The introducer of claim 1, wherein the at least one peripheral guide
2 wire comprises two peripheral guide wires and the at least one peripheral channel comprises
3 two peripheral channels, each for receiving one of the peripheral guide wires.

1 6. The introducer of claim 5, wherein the two peripheral channels are
2 located at diametrically opposed locations on the nose cone.

1 7. The introducer of claim 1 further comprising:

2 a trunk deployment catheter concentric with the axial guide wire and having at
3 least one inflatable deployment balloon at a distal end thereof; and

4 at least one peripheral deployment catheter, each concentric with one of the
5 peripheral guide wires and having at least one inflatable deployment balloon at a distal end
6 thereof.

1 8. The introducer of claim 7 further comprising:

2 the prosthesis for deployment in the body lumen, the prosthesis comprising a
3 trunk and at least one arm extending radially from the trunk, the prosthesis adapted to be
4 introduced into the lumen in a compressed configuration with the trunk concentric with the
5 trunk deployment catheter and each arm concentric with one of the peripheral deployment
6 catheters, the prosthesis adapted to be deployed in the lumen in an expanded configuration
7 with the trunk in the main lumen and each arm in one of the branch lumen.

1 9. The introducer of claim 8, wherein the prosthesis comprises a graft and
2 at least one stent.

1 10. The introducer of claim 9, wherein the at least one stent comprises:

2 a distal trunk stent portion expandable for deployment in a distal portion of the
3 main lumen distal the branch lumen;

4 a proximal trunk stent portion expandable for deployment in a proximal
5 portion of the main lumen proximal the branch lumen; and

6 at least one branch stent portion expandable for deployment in one of the
7 branch lumen.

1 11. The introducer of claim 10, wherein the trunk deployment catheter
2 comprises at least one inflatable deployment balloon for deploying the distal trunk stent
3 portion and at least one inflatable deployment balloon for deploying the proximal trunk stent
4 portion.

1 12. The introducer of claim 10, wherein the trunk deployment catheter
2 consists of only a single inflatable deployment balloon maneuverable for deploying both the
3 distal trunk stent portion and the proximal trunk stent portion.

1 13. The introducer of claim 10, wherein the distal trunk stent portion, the
2 proximal trunk stent portion and each branch stent portion comprise separate stents.

1 14. A nose cone for use with an introducer for insertion of a prosthesis in a
2 lumen from a proximal location outside the lumen to a distal location within the lumen, the
3 nose cone defining an axial conduit for receiving a first guide wire and at least one peripheral
4 channel spaced apart from the axial conduit for receiving a second guide wire.

1 15. The nose cone of claim 14, wherein the nose cone has a periphery and
2 each peripheral channel is open to the periphery of the nose cone.

1 16. The nose cone of claim 14, wherein the at least one peripheral channel
2 comprises two peripheral channels.

1 17. The nose cone of claim 16, wherein the peripheral channels are
2 diametrically opposed.

1 18. A unitary prosthesis for deployment in a distal location within the
2 lumen from a proximal location outside the lumen, the distal location positioned at a junction
3 of a main lumen and at least one branch lumen, the prosthesis comprising a trunk section and
4 at least one arm section extending radially from the trunk section.

1 19. The unitary prosthesis of claim 18, wherein the arm section is
2 approximately perpendicular to the trunk section.

1 20. The unitary prosthesis of claim 18, wherein the at least one arm section
2 comprises two arm sections.

1 21. The unitary prosthesis of claim 20, wherein the prosthesis is adapted to
2 be deployed at a junction wherein the main lumen comprises an aorta and each branch lumen
3 comprises a renal artery.

1 22. The unitary prosthesis of claim 18, wherein the prosthesis comprises a
2 graft and at least one stent.

1 23. The unitary prosthesis of claim 22, wherein the at least one stent
2 comprises:

3 a distal trunk stent portion expandable for deployment in a distal portion of the
4 main lumen distal the branch lumen;

5 a proximal trunk stent portion expandable for deployment in a proximal
6 portion of the main lumen proximal the branch lumen; and

7 at least one branch stent portion expandable for deployment in one of the
8 branch lumen.

1 24. The unitary prosthesis of claim 23, wherein the distal trunk stent
2 portion, the proximal trunk stent portion and each branch stent portion comprise separate
3 stents.

1 25. A method for implanting a prosthesis in a distal location within the
2 lumen from a proximal location outside the lumen, the distal location positioned at a junction
3 of a main lumen and at least one branch lumen, the prosthesis comprising at least one stent
4 and having a trunk and at least one arm, each arm for implantation into the branch lumen and
5 the trunk for implantation into the main lumen, the method comprising the steps of:

6 (a) providing an introducer comprising an outer sheath; an axial guide wire
7 and at least one peripheral guide wire slidable within the outer sheath;
8 a nose cone at a distal end of the outer sheath, the nose cone having an
9 axial conduit slidable over the axial guide wire and at least one
10 peripheral guide channel each for receiving one of the peripheral guide
11 wires, each peripheral guide wire comprising an inflatable anchor
12 balloon at a distal end thereof; a trunk deployment catheter concentric
13 with the axial guidewire and having at least one inflatable deployment
14 balloon; and at least one arm deployment catheter concentric with the
15 peripheral guide wire and having at least one inflatable deployment
16 balloon;

17 (b) providing the prosthesis inside the outer sheath with the trunk mounted
18 over the axial guide wire and at least one trunk stent portion mounted
19 over each inflatable deployment balloon of the trunk deployment
20 catheter and each arm mounted over one of the peripheral guide wires

- 21 and at least one arm stent portion mounted over each inflatable
22 deployment balloon of each arm deployment catheter;
- 23 (c) introducing the introducer into the lumen until reaching an implantation
24 position adjacent the branch lumen;
- 25 (d) maintaining the introducer in the implantation position while advancing
26 each peripheral guide wire distally through one of the peripheral
27 channels of the nose cone until each wire is positioned at a sufficient
28 depth within the corresponding branch lumen;
- 29 (e) inflating each anchor balloon on each peripheral guide wire to fix the
30 wire in a set position;
- 31 (f) advancing the prosthesis over the axial and peripheral guide wires until
32 each arm of the prosthesis is positioned at a sufficient depth within the
33 branch lumen, and
- 34 (g) inflating the deployment balloons to expand at least the trunk and arm
35 stent portions of the prosthesis to implant the prosthesis.

1 26. The method of claim 25, wherein the main lumen comprises an aorta
2 and the at least one branch lumen comprises the renal arteries, the prosthesis comprises two
3 arms, the introducer comprises two peripheral guide wires and two arm deployment
4 catheters, and the nose cone comprises two peripheral channels, the method further
5 comprising implanting the prosthesis at the junction of the aorta and renal arteries.

1 27. The method of claim 26 comprising repairing an aneurysm by
2 implanting the prosthesis.

1 28. The method of claim 25, wherein the prosthesis comprises a distal
2 trunk stent portion distal the branch lumen and a proximal trunk stent portion proximal the
3 branch lumen and implanting the prosthesis in step (g) comprises first inflating deployment
4 balloons to deploy the distal trunk stent portion and all arm stent portions, then deflating each
5 arm deployment balloon and retracting each arm deployment catheter at least to a position
6 proximal the proximal trunk stent portion, then inflating a deployment balloon to deploy the
7 proximal trunk stent portion.

1 29. The method of claim 28, wherein the trunk deployment catheter
2 comprises a distal deployment balloon and a proximal deployment balloon, the method
3 comprising inflating the distal deployment balloon prior to retracting the arm deployment
4 catheters and inflating the proximal deployment balloon after retracting the arm deployment
5 catheters.

1 30. The method of claim 28, wherein the trunk deployment catheter
2 comprises a single trunk deployment balloon for expanding both the distal trunk stent portion
3 and the proximal trunk stent portion, the method comprising inflating the single deployment
4 balloon to expand the distal trunk section, retracting the arm deployment catheters after
5 expanding the arm stent portions, deflating and partially retracting the trunk deployment
6 balloon to a position proximal the proximal stent portion, and re-inflating the trunk
7 deployment balloon to expand the proximal stent portion.

1 31. The method of claim 28 wherein step (f) further comprises advancing
2 the nose cone distal of the junction between the branch lumen and the main lumen.

1 32. A method for implanting a modular prosthesis in a distal location
2 within the lumen from a proximal location outside the lumen, the distal location positioned at
3 a junction of a main lumen and at least one branch lumen, the modular prosthesis comprising
4 a trunk module for implantation into the main lumen and comprising at least one stent and at
5 least one arm fitting, the modular prosthesis further comprising at least one arm module for
6 implantation into the branch lumen, the arm module adapted to interconnect with the arm
7 fitting of the trunk module and comprising at least one stent, the method comprising the steps
8 of:

- 9 (a) introducing a first introducer into the main lumen until reaching a first
10 implantation position adjacent the branch lumen, the first introducer
11 comprising an outer sheath; an axial guide wire slidable within the
12 outer sheath; a nose cone at a distal end of the outer sheath, the nose
13 cone having an axial conduit slidable over the axial guide wire; a trunk
14 deployment catheter concentric with the axial guidewire and having at
15 least one inflatable deployment balloon; the modular prosthesis inside
16 the outer sheath with the trunk module mounted over the axial guide

- 17 wire and at least one trunk stent portion mounted over each inflatable
18 deployment balloon of the trunk deployment catheter
- 19 (b) advancing the nose cone distally to a location distal of the junction of
20 the main lumen with the branch lumen;
- 21 (c) implanting the trunk module with each arm fitting aligned with a
22 corresponding branch lumen by inflating the trunk section deployment
23 balloons to expand the trunk stent portions;
- 24 (d) introducing a second introducer into the lumen to a second implantation
25 position, the second introducer comprising an outer sheath; an axial
26 guide wire and at least one peripheral guide wire slidable within the
27 outer sheath; a nose cone at a distal end of the outer sheath, the nose
28 cone having an axial conduit slidable over the axial guide wire and at
29 least one peripheral guide channel each for receiving one of the
30 peripheral guide wires, each peripheral wire comprising an inflatable
31 anchor balloon at a distal end thereof; a trunk deployment catheter
32 concentric with the axial guidewire and having at least one inflatable
33 deployment balloon; at least one arm deployment catheter concentric
34 with the peripheral guide wire and having at least one inflatable
35 deployment balloon; each arm module mounted over one of the
36 peripheral guide wires and at least one arm stent portion of each arm
37 module mounted over each inflatable deployment balloon of each arm
38 deployment catheter;
- 39 (e) maintaining the second introducer in the implantation position while
40 advancing each peripheral guide wire distally through one of the
41 peripheral channels of the nose cone and through one of the arm
42 fittings in the implanted trunk module until each peripheral guide wire
43 is positioned at a sufficient depth within the corresponding branch
44 lumen;
- 45 (f) inflating each anchor balloon on each peripheral guide wire to fix the
46 wire in a set position;

(g) advancing each arm module over one of the peripheral guide wires until each arm module is positioned at a sufficient depth within the branch lumen and in an interlocking position with one of the arm fittings of the trunk module;

(h) inflating each arm deployment balloon to expand at least the arm stent portions of each arm module to implant the arm module within the branch lumen and within the corresponding arm fitting of the trunk module.

33. The method of claim 32 wherein the first introducer and the second introducer are the same introducer, and step (c) is performed with each arm module and arm deployment catheter positioned within the outer sheath proximal of the proximal end of the trunk module, and step (d) comprises retracting the nose cone to a position aligned with the branch lumen.

34. A method for implanting a prosthesis in a distal location within the lumen from a proximal location outside the lumen, the distal location positioned at a junction of a main lumen and at least one branch lumen, the prosthesis having a compressed configuration and an expanded configuration and comprising at least one portion for implantation into the branch lumen, the method comprising the steps of:

(a) providing an introducer comprising an outer sheath; an axial guide wire and at least one peripheral guide wire slidable within the outer sheath; a nose cone at a distal end of the outer sheath, the nose cone having an axial conduit slidable over the axial guide wire and at least one peripheral guide channel for receiving the peripheral guide wire, the peripheral wire comprising an inflatable anchor balloon at a distal end thereof;

(b) introducing the introducer into the lumen until reaching an implantation position adjacent the branch lumen;

(c) maintaining the introducer in the implantation position while advancing the peripheral guide wire distally through the peripheral channel of the

- 17 nose cone until the wire is positioned at a sufficient depth the branch
18 lumen;
- 19 (d) inflating the anchor balloon to fix the peripheral guide wire in a set
20 position;
- 21 (e) advancing the prosthesis over the peripheral guide wire until at least a
22 portion of the prosthesis is positioned at a sufficient depth within the
23 branch lumen, and
- 24 (f) expanding at least a portion of the prosthesis to implant the portion of
25 the prosthesis in the branch lumen.

1 35. The method of claim 34 wherein the prosthesis is expanded in step (f)
2 by balloon-expansion.

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